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Outcomes Assessment

Hormone Replacement Therapy

Prepared for Kansas Medical Assistance Program in April, 2008

EXECUTIVE SUMMARY

Purpose of Intervention	The primary purpose of this intervention is to improve the pharmacotherapy of the symptoms of menopause by promoting the most clinically appropriate and cost-effective hormone replacement therapy (HRT).

Intervention	Intervention Type	Population-based mailing
	Intervention Mailing Date	February 2007
	Pre-intervention Period (Baseline)	August 2006 – January 2007
	Post-intervention Period (Post)	March 2007 – August 2007
	Number of Letters Mailed	630
	Number of Targeted Physicians	630
	Number of Targeted Patients	721
	Adjusted Targeted Patients	585

Changes in Clinical Indicators

Clinical Indicators	Baseline	Target Aug-07	% Change
Therapy Duration	536	460	-14.2%
Increased Risk of ADE	73	39	-46.6%
Total	609	499	-18.1%

Savings Calculation

Intervention-Related Drug Therapy	
Targeted Group: Actual Average Paid Amount Per Patient Per Month (Baseline)	$27.21
Targeted Group: Actual Average Paid Amount Per Patient Per Month (Post)	$26.88
Estimated Savings Per Patient Per Month	$0.33
Total Number of Targeted Patients	585
6-Month Total Savings	$1,168.25

BACKGROUND

In postmenopausal women, estrogens are effective for treating vasomotor symptoms, vaginal atrophy, and they also help prevent bone loss associated with osteoporosis. With the introduction of the Women's Health Initiative (WHI) results, many leading medical organizations now suggest that ERT/HRT be used for management of vasomotor symptoms, using the lowest dose for the shortest duration. Topical vaginal products should especially be considered when ERT/HRT is only being used for the treatment of vaginal atrophy. Labeling for estrogens has been updated with the following recommendations:[1,2]

- Other non-estrogen therapies should be carefully considered if ERT/HRT is being used for the sole purpose of osteoporosis prevention.
- Estrogens with or without progestins should not be used for the prevention of cardiovascular.

Per member spending and utilization of estrogen products continued to fall in light of findings from the WHI estrogen-plus-progestin trial and the estrogen-alone trial conducted by the National Institute Health (NIH).[3] Recent studies, including the WHI trial, have played an important role in the current treatment recommendations for ERT/HRT.

[1] Premarin® [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals Inc.: July 16, 2003.
[2] Murray L, Senior Editor. In: Physicians' Desk Reference, PDR Edition 58, 2004. Thomson PDR. Montvale, NJ. 2004.
[3] Novartis Pharmacy Benefit Report. Facts and Figures. 2004 Edition. East Hanover, NJ: Novartis Pharmaceuticals, 2004.

METHODOLOGY

Changes in intervention-related pharmacy dollars paid, pharmacy dollars paid per patient per month (PPPM), and number of pharmacy claims were examined. This intervention identified providers whose patients were affected by therapy duration and increased risk of adverse drug effects. To assess the impact of the intervention, pharmacy drug claims were reviewed from March 2007 through August 2007.

Clinical Criteria: Criteria, rationale, and text message(s) to providers are listed below. All physicians with at least one recipient "hitting" on criteria received letters.

- Therapy Duration
  The indicator identifies patients who have received more than 1 year of continuous estrogen or estrogen combination drug therapy.

  Rationale: Estrogens have been reported to increase the risk of endometrial carcinoma in postmenopausal women.[4] Studies have shown an increased risk of endometrial cancer in postmenopausal women exposed to exogenous estrogens for more than 1 year. Therefore, estrogen use for menopausal symptoms should use the lowest dose and be discontinued as soon as possible. Semiannual reassessment is recommended. Additionally, because the WHI reported increased risks of MI, stroke, invasive breast cancer, pulmonary emboli, and deep venous thrombosis in the estrogen and progestin group (risks for estrogen therapy alone are assumed to be similar), again, the lowest effective dose for the shortest duration should be instituted as consistent with treatment goals and risks for each individual woman.

  Sample Provider Paragraph:

  > According to submitted pharmacy claims data, it appears your patient has been receiving an estrogen or estrogen/progestin medication for longer than one year. The Women's Health Initiative (WHI) study showed a 24% overall increase in the risk of coronary heart disease in postmenopausal women, with an 81% increased risk of heart disease in the first year after starting treatment. Accordingly, hormone replacement therapy is only recommended for the management of vasomotor symptoms, using the lowest dose for the shortest duration, and should be discontinued as soon as possible. Please review the use of the identified estrogen or estrogen/progestin agent with your patient and consider if continued therapy is indicated to meet the treatment goals of the individual patient.

- Increased Risk of Adverse Drug Events
  The increased risk of ADE indicator identifies patients with a prescription claim for estrogen or estrogen combination product in the last 60 days with a contraindicated medical condition.

  Rationale: In certain contraindicated conditions, use of hormone replacement therapy can result in serious adverse drug events with potential long-term complications (e.g., cancer).

[4] Kastrup EK, Ed. Drug Facts and Comparisons (EFacts). Facts & Comparisons. St. Louis. 2005.

Sample Provider Paragraph:

Based on submitted pharmacy and medical claims data, it appears your patient is receiving hormone replacement therapy and has a history of breast cancer. With the exception of patients being treated for metastatic disease, use of estrogen products is contraindicated in patients with a history of breast cancer. In The Women's Health Initiative study, the risk of breast cancer was increased by 24% in women on estrogen/progestin therapy for five years. Please review the use of hormone replacement therapy in your patient and determine if the benefits of therapy outweigh any risk for an adverse event.

Definitions:

Adjusted Target Patients – All patients of physicians who were included in the intervention, who had pharmacy claims and were active plan members throughout the post-intervention time period. Additionally, when outcomes are performed, these patients' pre-intervention (baseline) hits are re-evaluated to make certain that the status of clinical indicators haven't changed for each patient due to late pharmacy and medical claims.

Intervention Related Drugs – Estrogen replacement therapy, letrozole, anastrozol, exemestane, and estradiol.

RESULTS

Characteristics

Table 1 describes the patient population included in the population-based intervention based upon mean age, gender, number of providers, average number of prescriptions per patient per month, and utilization of intervention-related drugs at baseline. As can be seen from the table, the target group was seeing 3.9 providers, receiving 9.4 prescriptions per month, and utilizing 1.0 intervention-related drug during the baseline period.

Table 1: Patient Characteristics

	Target (N=585)
Mean Age	50.6
Percentage Male	0.0%
Percentage Female	100.0%
Number of Providers	3.9
Average Number of Prescriptions PPPM*	9.4
Utilization of Intervention-Related Drugs**	
Average Number of Drugs***	1.0
Average Number of Claims	5.4
Average Days Supply	157.9
Average Amount Paid	$163.27

* Number of prescriptions per patient per month (PPPM) is the average for the 6 month baseline period

** Based on 6 months of baseline claims data

*** A distinct drug is defined by using a coding system similar to the Hierarchical Ingredient Code List (HICL) in that distinct drugs are identified at the ingredient level.

Therapy Duration

Table 2 displays the changes in those target patients who were flagged for therapy duration. Overall, this indicator decreased by 14.2% for the target group.

Table 2: Changes in Therapy Duration

Therapy Duration	Target		
	Baseline	Aug-07	% Change
Long Duration: ERT/HRT	536	460	-14.2%

Increased Risk of ADE

The changes in the number of patients flagged for being at an increased risk of adverse drug events are displayed in Table 3. Overall, there was a 46.6% reduction in the number of target patients.

Table 3: Changes in Increased Risk of ADE

Increased Risk of ADE	Baseline	Target Aug-07	% Change
Estrogen use and breast cancer	1	0	-100.0%
Estrogen use and uterine or endometrial cancer	5	2	-60.0%
Estrogen use and abnormal genital bleeding	9	4	-55.6%
Estrogen use and DVT/PE	11	9	-18.2%
Estrogen use and recent MI/Stroke	1	1	0.0%
Estrogen use and history of thrombophlebitis	9	6	-33.3%
Estrogen use and pregnancy	1	0	-100.0%
Estrogens and gallbladder disease	36	17	-52.8%
Total	73	39	-46.6%

The overall savings for the intervention is calculated in Table 4. Per patient per month (PPPM) drug amount paid for intervention-related drugs was calculated for the target group for the six-month baseline and six-month post-intervention periods. The post-period PPPM amount paid for the target group was subtracted from the baseline PPPM amount paid to obtain the estimated PPPM savings. The PPPM savings was then multiplied by the number of intervention months and number of target patients.

As a result of the intervention, the estimated per patient per month paid amount for intervention-related drugs decreased $0.33 for the target group. This yields an overall estimated savings of $1,168 in amount paid for intervention-related drugs during the six-month post-intervention period.

Table 4: Total Drug Savings

Savings Calculation:	
Targeted Group: Actual Average Paid Amount Per Patient Per Month (Baseline)	$27.21
Targeted Group: Actual Average Paid Amount Per Patient Per Month (Post)	$26.88
% Change in Target Group from Baseline to Post	-1.22%
Estimated Savings Per Patient Per Month	$0.33
Total Number of Targeted Patients	585
6-Month Total Savings	$1,168.25

LIMITATIONS

A control group was not utilized for this intervention. This limited the comparisons that could be performed in the analysis. Therefore, instead of being able to compare an intervention group with a non-intervention group, the analysis is essentially limited to changes in the intervention group before and after intervention.

The time frame of 6 months may not capture the full extent of the impact of the intervention. Providers may be required some time before they can change their patient's drug regimens. Additionally, if this study included only users of chronic medications, this may have more accurately reflected the pharmacy cost changes in both groups.

CONCLUSIONS

This intervention focused on improving prescribing practices and reducing the overall cost of care. Overall, the intervention was successful in reducing the total number of clinical indicators for target patients by 18.1%.

In terms of financial outcomes, the amount paid for total drugs decreased $0.33 in the post-intervention period. This yielded an overall estimated savings of $1,168 in intervention-related drug expenditures during the six-month post-intervention period.